

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 15-1084V

Filed: September 28, 2017

To Be Published

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STEVEN ZEBOFSKY,

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Petitioner,

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v.

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SECRETARY OF HEALTH  
AND HUMAN SERVICES,

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Respondent.

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Ruling on Entitlement (Non-Table);  
Causation in Fact; Findings of Fact;  
Dual Vaccines; Non-Covered  
Pneumococcal Vaccine; Influenza (Flu)  
Vaccine; Shoulder Injury Related to  
Vaccine Administration (SIRVA);  
Special Processing Unit (SPU)

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*Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.*

*Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.*

### **RULING ON ENTITLEMENT**<sup>1</sup>

**Dorsey**, Chief Special Master:

On September 28, 2015, Steven Zebofsky (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that he suffered injury to his right shoulder caused in fact by the influenza (“flu”) vaccine he received on October 18, 2014. Petition at 1, ¶¶ 3, 11. Petitioner further alleges that he received the vaccine in the United States, suffered the residual effects of his injury for more than six months, and has never received compensation for his injury, alleged as vaccine caused. *Id.* at ¶¶ 3, 11-13. The case was assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

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<sup>1</sup> Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

## I. Procedural History and the Parties' Dispute

Along with his petition, petitioner filed medical records and a statement of completion. See Exhibits 1-4 (ECF No. 1); Statement of Completion (ECF No. 2). In the petition, he acknowledges that he suffered "a previous right shoulder injury in 2012" but claims it had resolved by the time he received the flu vaccine. Petition at ¶ 2. Additionally, the proof of vaccination filed with the petition shows that on October 18, 2014, petitioner received the flu vaccine, and also received a vaccine not covered by the Vaccine Program, Pneumovax 23.<sup>3</sup> Exhibit 1 at 1, 4.

During the November 9, 2015 initial status conference, respondent's counsel indicated that respondent wished to see additional records regarding the arm in which petitioner's influenza vaccination was administered and his earlier shoulder injury. Petitioner filed further documentation from Walgreens and records from the physical therapy he received for his earlier shoulder injury. See Exhibits 5-6, filed Dec. 29, 2015 and Jan. 6, 2016 (ECF Nos. 12-13). After seeking subpoena authority, petitioner filed additional documentation from Walgreens which shows he received both vaccines in his right arm. See Exhibit 7, filed Mar. 18, 2016 (ECF No. 19).

On May 20, 2016, respondent filed a status report indicating he was willing to explore a litigative risk settlement. (ECF No. 22). After four months of negotiations, petitioner informed the undersigned that the parties were unable to reach a settlement in this case. Status Report, filed Sept. 30, 2016 (ECF No. 31). Petitioner explained that the parties' disagreement stems from the fact that petitioner received both the influenza and adult pneumococcal vaccinations in his injured shoulder. *Id.* During an October 4, 2016 status conference with the staff attorney managing this SPU case, respondent's counsel confirmed that she was not aware of another issue with petitioner's claim. See Order, issued Oct. 4, 2016, at 1 (ECF No. 32). She argued that petitioner would never be able to establish causation in a case such as this one since it would be impossible to show which vaccine caused petitioner's injury. See Order, issued Oct. 28, 2016, at 1 (ECF No. 33).

A call was scheduled with the undersigned for October 25, 2016. The parties were informed it would not be a formal Rule 5 status conference but the undersigned would discuss her findings of fact and conclusions regarding petitioner's receipt of two vaccinations in his injured arm. See Order, issued Oct. 4, 2016, at 2. Due to a last

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<sup>3</sup> "There are two types of pneumococcal vaccines . . . pneumococcal conjugate and polysaccharide vaccine[s]." *Bundy v. Sec'y of Health & Human Services*, No. 12-769V, 2014 WL 348852, at \*1 (Fed. Cl. Spec. Mstr. Jan. 8, 2014). Only pneumococcal conjugate vaccines, routinely administered to children, are covered by the Vaccine Program. *Id.*; see *Morrison v. Sec'y of Health & Human Services*, No. 04-1683V, 2005 WL 2008245, at \*1 (Fed. Cl. Spec. Mstr. July 26, 2005) (describing how and when pneumococcal conjugate vaccines were added to the Vaccine Table). The Pneumovax 23 vaccine, manufactured by Merck & Co. LLC, is a polyvalent vaccine not covered by the Vaccine Program. <https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm179996.htm> (last visited May 9, 2017). A discussion of the two types of pneumococcal vaccine also can be found at the Centers for Disease Control and Prevention (CDC) website. See <https://www.cdc.gov/vaccines/vpd/pneumo/public/index.html> (last visited May 9, 2017).

minute scheduling conflict for the undersigned, the staff attorney spoke to the parties instead. See Order, issued Oct. 28, 2016, at 1.

The staff attorney began by referencing the Federal Circuit's holding in *Walther*, regarding the burden to eliminate an alternative cause. See *id.* at 1-2; *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146 (Fed. Cir. 2007). She suggested that by arguing petitioner can never establish causation in a case such as this when both a covered and non-covered vaccination were administered in the injured arm, respondent seems to be asserting that petitioner always has the burden of eliminating the non-covered vaccine as an alternate cause. See Order, issued Oct. 28, 2016, at 1. Respondent appears to ignore the Federal Circuit's conclusion in *Walther*, "that the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case." 485 F.3d at 1150. Examining §13(a)(1) of the Vaccine Act, the Federal Circuit determined that "the government bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case." *Id.* at 1150-51. The staff attorney communicated the undersigned's offer to allow the parties to brief this issue but also suggested the undersigned could hold a formal Rule 5 status conference if the parties preferred. See Order, issued Oct. 28, 2016, at 2. The parties agreed that a Rule 5 status conference would be more helpful in this case, and the call was scheduled for November 29, 2016. See *id.*

During the Rule 5 status conference,<sup>4</sup> the undersigned informed the parties there was sufficient evidence in the medical records to conclude that petitioner's right shoulder injury resulted from the influenza vaccination he received rather than the adult pneumococcal vaccination. See Ruling on Facts and Rule 5 Scheduling Order ("Ruling on Facts"), issued Dec. 15, 2016, at 2 (ECF No. 36). She discussed this evidence in detail and expressed her willingness to issue a factual finding. See *id.* at 3. The parties agreed, and the undersigned issued a ruling on December 15, 2016. In the ruling, the undersigned ordered the parties to file a joint status report regarding their settlement discussions. See *id.* at 4.

On January 31, 2017, the parties filed their joint status report, indicating they "continued settlement negotiations following the Rule 5 Conference on December 13, 2016, but have reached an impasse." (ECF No. 37). They requested that the undersigned "enter a decision on entitlement and an assessment of damages." *Id.* In response to an email communication from the OSM staff attorney, respondent's counsel indicated that respondent wished to file a Rule 4 report. See Informal Remark, dated Feb. 8, 2017. Respondent filed his Rule 4 report on February 27, 2017. (ECF No. 40).

On March 24, 2017, the staff attorney held a status conference with the parties to discuss the next steps in the case. See Order, issued Apr. 10, 2017, at 3 (ECF No. 41). During the call, the staff attorney discussed the undersigned's factual ruling, the guidance from the Federal Circuit expressed in *Walther*, and the contents of respondent's Rule 4 report with the parties. She clarified that the undersigned's

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<sup>4</sup> Although characterized as a Rule 5 status conference, the undersigned recognizes that respondent had not yet set forth his written objections in a Rule 4 report. See Vaccine Rule 5.

December 15, 2016 ruling was a factual ruling based on the evidence found in the medical records. She explained that the undersigned had not yet addressed the issue of causation and thus, was providing petitioner the opportunity to file an expert report and additional evidence to establish that petitioner has met his burden regarding causation. See *id.* Because the injury of shoulder injury related to vaccine administration (“SIRVA”) was not added to the Vaccine Injury Table until March 21, 2017,<sup>5</sup> petitioner must establish actual causation by satisfying the three pronged test set forth in *Althen*.<sup>6</sup> Following petitioner’s filings, respondent would be given an opportunity to provide an expert report and other evidence he may wish to file.

As an example of the issues petitioner should address, the staff attorney mentioned petitioner’s earlier right shoulder pain. See Order, issued Apr. 10, 2017, at 3-4. When petitioner last sought treatment for this injury in July 2012, his orthopedist recommended arthroscopic surgery. See Exhibit 3 at 17. Although it appears that injury resolved, the staff attorney noted there was nothing in the record to indicate how or when this occurred. The staff attorney suggested a detailed affidavit from petitioner may be helpful to explain the events between petitioner’s earlier shoulder pain and the pain he experienced in the fall of 2014. See Order, issued Apr. 10, 2017, at 4.

On June 23, 2017, petitioner filed the expert report of Dr. G. Russell Huffman and a second affidavit<sup>7</sup> from petitioner regarding his earlier shoulder pain. See Exhibits 9-10 (ECF No. 44). After reviewing these documents, the undersigned directed the staff attorney to hold a call with the parties to communicate her intention to issue a ruling on entitlement. She also indicated she wanted to know, as soon as possible, whether respondent wished to supplement the record in this case prior to her ruling. The staff attorney held a call with the parties on June 29, 2017.

During the call, respondent’s counsel indicated she had not reviewed petitioner’s June 23, 2017 filings or discussed the case with respondent. The staff attorney informed her that the undersigned wished to know respondent’s preference within two weeks but would allow respondent 30 days because of the July 4 holiday. On August 1,

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<sup>5</sup> Originally, the effective date for the new rule was February 21, 2017. Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294 (Jan. 19, 2017) (to be codified at 42 C.F.R. pt. 100). This effective date was delayed until March 21, 2017. Delay of Revisions to the Vaccine Injury Table, 82 Fed. Reg. 11321 (Feb. 22, 2017) (to be codified at 42 C.F.R. pt. 100).

<sup>6</sup> To be successful on a causation-in-fact claim, petitioners must provide: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y of Health & Human*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). All three prongs of the *Althen* test must be satisfied by preponderant evidence. *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 119, 132 (2011), *aff’d per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012) (finding that “[w]hen a petitioner seeks to demonstrate causation in fact by meeting the three *Althen* requirements, each of those requirements must be proven by a preponderance of the evidence”).

<sup>7</sup> A few days prior to the undersigned’s December 15, 2016 ruling, petitioner filed an affidavit in which he candidly admitted that he could not now recall which vaccination he received first or where in his right shoulder the vaccinations were given. See Exhibit 8, filed on Dec. 13, 2016 (ECF No. 35).

2017, respondent filed a status report indicating he “does not wish to further supplement the record.” (ECF No. 46).

The matter is now ripe for adjudication.

## **II. Relevant Medical History**

The medical records show that petitioner experienced right shoulder pain at the beginning of 2012. He received physical therapy at Gold Coast Physical Therapy Associates (“Gold Coast PT”) from early March thru April 2012. See Exhibit 5 at 103-134. The intake form lists petitioner’s primary care physician as Dr. Avni, but indicates he was referred to Gold Coast PT by Dr. Bergman. Exhibit 5 at 103.

On May 29, 2012, petitioner sought treatment from Dr. Routman at Atlantis Orthopaedics. See Exhibit 3 at 21-22. His pain was described as dull and aching, beginning in January 2012, and having no known cause or injury. *Id.* at 21. Dr. Routman instructed petitioner to continue his home exercise program. *Id.* at 22.

Petitioner visited Dr. Routman again on June 28 and July 6, 2012. *Id.* at 15-20. An MRI was performed on July 3, 2012. *Id.* at 39-42. At the July 6 visit, Dr. Routman diagnosed petitioner with adhesive capsulitis. Noting that petitioner had injections and physical therapy, Dr. Routman informed petitioner he was a candidate for arthroscopic surgery. *Id.* at 17. In his second affidavit, petitioner states that his problem was resolved after the July 2012 visit. Exhibit 10 at ¶ 4. He claims he did not have a problem with his shoulder after that until receiving the vaccinations administered on October 18, 2014. *Id.* The medical records from Dr. Routman support this assertion as they show petitioner did not return to Atlantis Orthopaedics until October 30, 2014, when he complained of right shoulder pain, stating that it began 12 days earlier after receiving the flu vaccine. Exhibit 3 at 11.

From July 2012 until October 2014, petitioner continued to receive treatment from his primary care physician, Dr. Avni. No complaint of right shoulder pain is found in any of the records from these visits. See Exhibit 2 at 1-20. However, petitioner is noted to have arthritis as well as other common conditions such as high blood pressure and high cholesterol. See, e.g., *id.* at 8. Petitioner first complained of shoulder pain to Dr. Avni on October 20, 2014. *Id.* at 23. He described symptoms of fever, chills, and right shoulder pain six hours after receiving the flu and pneumococcal vaccines. *Id.* Dr. Avni assessed petitioner as having an adverse vaccine reaction. *Id.* at 24.

After examining petitioner on October 30, 2014, Dr. Routman described him as having “a painful but strong right shoulder.” Exhibit 3 at 13. Right shoulder x-rays revealed no fractures or dislocations but “a large calcium deposit in the sub-acromial space.” *Id.* Dr. Routman administered a sub-acromial injection using half-strength Deprol. *Id.* In the record from this visit, it is noted that petitioner reported his pain as beginning after he received “the flu shot to [sic] high in the arm.” *Id.* at 13.

Petitioner returned to Dr. Routman on January 22, 2015. Reporting that the October 30, 2014 injection had helped (*id.* at 7), petitioner described his pain was “mild

and improving” (*id.* at 5). Dr. Routman informed petitioner he was a good candidate for another sub-acromial injection or arthroscopic removal of the calcium deposits in his shoulder. Petitioner indicated he would consider a course of physical therapy. *Id.* at 7.

During the remainder of January thru February 2015, petitioner was treated at Holy Cross Medical Group for hip and back pain. See Exhibit 4 at 4-16, 19-20, and 31-46. He also received physical therapy from Gold Coast PT. See Exhibit 5 at 10-51. On April 6, 2015, he was seen by Dr. Avni for a burning sensation in his lower leg. See Exhibit 2 at 26-28. It appears he did not mention his right shoulder pain at any of these visits. At the April 6, 2015 visit with Dr. Avni, petitioner denied any back pain. See *id.* at 27.

Petitioner again sought treatment for his right shoulder pain on April 14, 2015, this time from Dr. McKay at Holy Cross Medical Center. See Exhibit 4 at 23-25. Several notations in the record from this visit indicate petitioner attributed his injury to both the flu and pneumococcal vaccines. *Id.* at 23, 26. However, one notation which may have been written by petitioner says “flu shot given in wrong part of arm and has caused pain since.” *Id.* at 26. Dr. McKay diagnosed petitioner as suffering from calcific tendinitis and prescribed physical therapy. *Id.* at 27. From April 23 to May 23, 2015, petitioner received physical therapy for his right shoulder pain at Gold Coast PT. See Exhibit 5 at 52-78. On a follow-up visit to Dr. McKay on May 11, 2015, petitioner indicated that his condition had improved and he felt only occasional pain, especially when performing bench press exercises. Exhibit 4 at 19.

### **III. Findings of Fact**

On December 15, 2016, the undersigned issued a ruling, finding that, as a factual matter, petitioner’s right shoulder injuries resulted from the influenza vaccination administered in his right arm on October 18, 2014, and not the adult pneumococcal vaccination administered the same day in the same arm. Ruling on Facts at 3. The undersigned based her finding upon entries in the medical records created closer in time to the vaccinations when petitioner attributed his injury solely to the influenza vaccine. See *id.* The undersigned recognized there were times in the medical records when petitioner referenced both vaccinations (see, e.g., exhibit 2 at 23) and that now he cannot recall the order or exact location of the vaccinations he received (see exhibit 8 at 3). However, she observed that, closer in time to the vaccinations, petitioner stated that the vaccination which was given too high and which caused the swelling and pain he experienced was the influenza vaccination. Ruling on Facts at 3.

The undersigned stressed Federal Circuit precedent which states that it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. *Id.*; see *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence).

#### **IV. Causation in Fact**

Because the petition in this case was filed prior to the effective date for the revised Table, March 21, 2017, petitioner must provide preponderant evidence establishing causation in fact. He must satisfy the three prong test set forth in *Althen*. 418 F.3d 1278; *see also supra* note 6 (quoting the exact wording of the three prongs).

In support of her claim, petitioner submitted medical records, two affidavits, and an expert report. Respondent declined to submit an expert report, relying instead on his Rule 4 report.

##### **A. Petitioner's Expert Report**

Petitioner's expert, Dr. G. Russell Huffman, is well-qualified to opine in this case. He is "an academic shoulder and elbow surgeon and an Associate Professor of Orthopedic Surgery at the University of Pennsylvania where [he has] practiced for the past 21 years." Exhibit 9 at 1. He treats patients with shoulder and elbow problems, overseeing 3,000 patient visit and performing over 450 surgeries per year. He is the "director of Penn's nationally accredited Shoulder and Elbow Fellowship," has authored over 100 orthopedic publications, and has lectured nationally and internationally. *Id.*

In his expert report, Dr. Huffman states that "[i]t is [his] opinion that the facts support SIVRA in the case of Mr. Steven Zebofsky as a direct result of an influenza vaccination administered on October 18, 2014." *Id.* Dr. Huffman describes his opinion as "within a reasonable degree of medical certainty" and adds that petitioner's injury "fits into the SIRVA classification." *Id.* at 4.

With regard to Prong 1, Dr. Huffman states that "a credible theory of immunogenic and vaccine related bursitis, adhesive capsulitis and other local adverse reactions within the shoulder joint is very well-established and acknowledged by both the medical community, the Institute of Medicine and the Health Resources and Services Administration." *Id.* at 5 (article citations omitted). Indeed, SIRVA following the administration of the influenza vaccine was included in the revised Table. *See supra* note 5 (for federal register citations).

Considering the specific facts in petitioner's case, Dr. Huffman first addresses the issue of petitioner's earlier right shoulder pain. He opines that "the fact that Mr. Zebofsky had a prior history of calcific tendinopathy and bursitis does not disprove nor preclude his subsequent adverse response to the influenza vaccination." Exhibit 9 at 5. He states that "patients may go decades with evident radiographic calcific tendinopathy with absolutely no symptoms." *Id.* Pointing to the information in petitioner's medical records, Dr. Huffman notes that petitioner's symptoms were improving in April 2012, and there is no evidence of symptoms or treatment in the 30 months prior to vaccination. *Id.* He contrasts this lack of evidence with consistent and clear documentation of shoulder pain immediately following vaccination in the records from "at least two independent orthopaedic surgeons, a primary care provider and petitioner's treating physical therapist." *Id.*

Dr. Huffman opines that the facts of petitioner's case fit recommendations made in the 2011 Institute of Medicine (IOM) Report regarding the proposed addition of

SIRVA to the Table. *Id.* (citation on following page). He credits petitioner's description of vaccination too high on the arm and notes Dr. Avni's diagnosis of an adverse vaccine reaction. *Id.* at 2-3. Dr. Huffman maintains that the fact petitioner received "both the pneumococcal and influenza vaccinations is irrelevant in this case, unless there is credible evidence or documentation that the Pneumovax 23 vaccination somehow inhibits or prevents SIRVA type reactions from influenza." *Id.* at 4.

When discussing the timing of petitioner's injury, Dr. Huffman points to a "documented clear temporal association between the vaccination being administered and subsequent onset of severe, persistent symptoms." *Id.* at 6. He describes petitioner's pain as occurring within six hours of vaccination and continuing for at least six months. *Id.* at 4, 6.

### **B. Respondent's Rule 4 Report**

In his report, respondent asserts that compensation is not appropriate because "[l]ooking at the totality of evidence, petitioner has not met the burden of proving a *prima facie* case under the Vaccine Act." Rule 4 Report at 12. Respondent mentions petitioner's "previous right shoulder pain" (*id.* at 2), but respondent's counsel clearly indicated respondent did not consider this earlier pain to be a weakness in petitioner's case. See Order, issued Apr. 10, 2017, at 4. On numerous occasions, respondent's counsel indicated the primary issue with petitioner's claim is the fact that petitioner received both the influenza and adult pneumococcal vaccinations in his injured shoulder. See *supra* Section II. Respondent maintains that "none of petitioner's treating physicians express the opinion that petitioner's right shoulder pathology was caused by the October 18, 2014 flu vaccine." Rule 4 Report at 7. However, as Dr. Huffman noted, Dr. Avni diagnosed petitioner with an adverse vaccine reaction on October 20, 2014. See Exhibit 2 at 24; Exhibit 9 at 3. Additionally, Dr. Huffman has provided a medical opinion in support of petitioner's claim.

Respondent does not discuss the holding in *Walther* but cites to other caselaw indicating respondent may provide evidence of an alternative cause to counter petitioner's *prima facie* case. Rule 4 Report at 11 (citing *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373 (Fed. Cir. 2012); *de Bazan*, 539 F.3d 1347). The undersigned notes, however, that respondent has offered no evidence other than the fact that petitioner received the pneumococcal vaccination. Dr. Huffman characterized the administration of this other vaccination as "irrelevant" without further evidence to show it would inhibit or prevent the effects of the flu vaccine in some way. Exhibit 9 at 4. Respondent has not provided this evidence.

### **V. Conclusion**

After reviewing the medical records, affidavits, and expert report submitted by petitioner, the undersigned concludes that petitioner has established a *prima facie* case for causation in fact. He has satisfied the three prong test in *Althen* by preponderant evidence. Respondent has not provided evidence to counter the evidence submitted by petitioner or to establish an alternative cause for petitioner's injury.



In view of the submitted evidence, including the medical records and findings of fact, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey  
Chief Special Master